

Atty. Dkt. No. 029318-0988

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Tuula RYDE et al.
Title: METHOD OF TREATMENT
USING NANOPARTICULATE
FIBRATE FORMULATIONS
Appl. No.: 10/692,855
Filing Date: 10/27/2003
Examiner: Konata M. George
Art Unit: 1616
Confirmation Number: 9261

TERMINAL DISCLAIMER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Your Petitioners, Elan Pharma International, Ltd., having its principal place of business at Monksland, Athlone, County Westmeath, Ireland (previously Will House, Shannon Business Park, Shannon, Co. Clare, Ireland), and Fournier Laboratories Ireland Ltd. having its principal place of business at 12 South Mall, Cork DX2002, Ireland, represent that they are the owners of the entire right, title, and interest in and to U.S. Patent Application Serial No. 10/692,855, filed 10/27/2003, which is a division of U.S. Patent Application No. 10/444,066, filed 5/23/2003, by virtue of an Assignment filed and recorded on 08/25/03, on Reel/Frame 014429/0905, in the United States Patent and Trademark Office, a copy of which is attached hereto as APPENDIX A.

Your Petitioners, Elan Pharma International, Ltd. and Fournier Laboratories Ireland Ltd., hereby disclaim the terminal part of the term of any patent granted on U.S. Patent Application 10/692,855 which would extend beyond the full statutory term, as shortened by

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any terminal disclaimer, of any patent granted on U.S. Patent Application 10/444,066, and hereby agrees that any patent so granted on U.S. Patent Application 10/692,855 shall be enforceable only for and during such period that the legal title to any patent granted on U.S. Patent Application 10/444,066 shall be the same as the legal title to any patent granted on U.S. Patent Application 10/692,855, this agreement to run with any patent granted on U.S. Patent Application 10/692,855 and to be binding upon the grantee, its successors or assigns.

In making the above disclaimer, Petitioners do not disclaim any terminal part of any patent granted on U.S. Patent Application 10/692,855, prior to the full statutory term of any patent granted on U.S. Patent Application 10/444,066 as defined in 35 U.S.C. §§154-156 and 173, in the event that any patent granted on U.S. Patent Application 10/444,066 expires for failure to pay a maintenance fee, is held unenforceable or is found invalid in a final judgment by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR §1.321(a), has all claims canceled by a reexamination certificate or as a result of an interference proceeding, or is otherwise not deemed to provide the rights conveyed by 35 USC §154, prior to the full statutory term of any patent granted on U.S. Patent Application 10/444,066 as defined in 35 USC §§154-156 and 173, except for the separation of legal title stated above. Further, Petitioners do not disclaim any terminal part of a patent granted on U.S. Patent Application 10/692,855 that would extend beyond the present termination of any patent granted on U.S. Patent Application 10/444,066, in the event that such present term is extended by virtue of compliance with the conditions for term extension of any present or future patent term extension provisions of the patent law, including but not limited to 35 U.S.C. §§155, 155A or 156, and without waiving Petitioners' right to extend the term of a patent granted on U.S. Patent Application 10/692,855 to the extent provided by law.

The undersigned, being the Attorney of Record for U.S. Patent Application 10/692,855, and duly authorized to act on behalf of Petitioners, certifies that she has reviewed the Assignment attached as APPENDIX A, and to the best of her knowledge and belief, legal title to U.S. Patent Application 10/692,855 and any patent granted on U.S. Patent Application 10/444,066 rests with Petitioners, Elan Pharma International, Ltd. and Fournier Laboratories Ireland Ltd. The undersigned declares that all statements made herein of her own knowledge are

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true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing therefrom.

Respectfully submitted,

Date 29 August 2007By B. L. B. 35,087
for

FOLEY & LARDNER LLP
Customer Number: 31049
Telephone: (202) 672-5538
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Michele M. Simkin
Attorney for Applicant
Registration No. 34,717

APPENDIX A



UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

MARCH 19, 2004

PTAS



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FOLEY & LARDNER
MICHELE M. SIMKIN
WASHINGTON HARBOUR
3000 K STREET, N.W., SUITE 500
WASHINGTON, DC 20007-5143UNITED STATES PATENT AND TRADEMARK OFFICE
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THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 08/25/2003

REEL/FRAME: 014429/0905
NUMBER OF PAGES: 5

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

RYDE, TUULA

DOC DATE: 06/03/2003

ASSIGNOR:

GUSTOW, EVAN E.

DOC DATE: 06/03/2003

ASSIGNOR:

RUDDY, STEPHEN B.

DOC DATE: 06/03/2003

ASSIGNOR:

JAIN, RAJEEV

DOC DATE: 06/03/2003

ASSIGNOR:

PATEL, RAKESH

DOC DATE: 06/03/2003

ASSIGNOR:

WILKINS, MICHAEL JOHN

DOC DATE: 07/29/2003

014429/0905 PAGE 2

ASSIGNEE:

ELAN PHARMA INTERNATIONAL, LTD.
WIL HOUSE, SHANNON BUSINESS PARK
SHANNON, CO.. CLARE, IRELAND

ASSIGNEE:

FOURNIER LABORATORIES IRELAND LTD.
12 SOUTH MALL
CORK DX 2002, IRELAND

SERIAL NUMBER: 10444066
PATENT NUMBER:

FILING DATE: 05/23/2003
ISSUE DATE:

DOROTHY WILLIAMS, PARALEGAL
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

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AUG 29 2007

Atty. Dkt. No. 029318-0949

FORM PTO-1595 (modified)

(Rev 6-93)

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08-29-2003



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2 SHEET

U.S. DEPARTMENT OF COMMERCE

Patent and Trademark Office

To the Director of the United States Patent and Trademark Office

ne attached original documents or copies thereof.

1. Name of conveying party(ies):

Tuula RYDE
Evan E. GUSTOW
Stephen B. RUDDY
Rajeev JAIN
Rakesh PATEL
Michael John WILKINS



2. Name and address of receiving party(ies):

ELAN PHARMA INTERNATIONAL, LTD.
WIL House, Shannon Business Park
Shannon, Co. Clare, Ireland
and
FOURNIER LABORATORIES IRELAND LTD.
12 South Mall, Cork DX 2002, Ireland

Additional conveying party(ies) NO

3. Nature of conveyance:

ASSIGNMENT

Execution Date:

June 3 & July 29, 2003

Additional name(s) & address(es) attached? NO

4. Application number(s) or patent number(s):

If this is being filed together with a new application, the execution date of the application is:

A. Patent Application Number(s):

~~10/444,066~~
10/444,066

B. Patent Number(s):

Additional numbers attached? NO

5. Name and address of party to whom correspondence concerning document should be mailed:

Michele M. Simkin
FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5143

6. Total number of applications/patents involved: 1

7. Total fee (37 C.F.R. § 3.41): \$40.00

☒ Check Enclosed

Charge to deposit account

8. Deposit account number: 19-0741

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9. Statement and signature:

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document. The Commissioner is hereby authorized to charge any additional recordation fees which may be required in this matter to the above-identified deposit account.

Michele M. Simkin

Aug 25, 2003

Name of person signing

Signature

Date

Total number of pages including cover sheet, attachments, and document: 5

08/27/2003 6TON11 00000161 10444066

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002.1068306.1

ASSIGNMENT - WORLDWIDE

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each undersigned inventor has sold and assigned, and by these presents hereby sells and assigns, unto

name and
address of
assignee(s)

ELAN PHARMA INTERNATIONAL, LTD.
WIL House, Shannon Business Park, Shannon, Co. Clare, Ireland
and
FOURNIER LABORATORIES IRELAND LTD.
12 South Mall, Cork DX 2002, Ireland

its successors and assigns, the entire right, title and interest, so far as concerns the United States and the Territories and Possessions thereof and all foreign countries in and to the invention in

title of
invention

NANOPARTICULATE FIBRATE FORMULATIONS

as set forth in this United States Patent Application

check one

☐ executed concurrently herewith

☐ executed on

☒ Serial No. 10/444,066 Filed 05/23/2003

said application for United States Letters Patent, including all divisional, renewal, substitute, continuation and Convention applications based in whole or in part upon said inventions or upon said applications, and any and all Letters Patent and reissues and extensions of Letters Patent granted for said inventions or upon said applications and every priority right that is or may be predicated upon or arise from said inventions, said applications, and said Letters Patent; said Assignee being hereby authorized to file patent applications in any or all countries on any or all said inventions in the name of the undersigned or in the name of said Assignee or otherwise as said Assignee may deem advisable, under the International Convention or otherwise; the Commissioner of Patents and Trademarks of the United States of America being hereby authorized to issue or transfer all said Letters Patent to said Assignee in accordance herewith; this assignment being under covenant, not only that full power to make the same is had by the undersigned, but also that such assigned right is not encumbered by any grant, license, or other right theretofore given, and that the undersigned will do all acts reasonably serving to ensure that the said inventions, patent applications and Letters Patent shall be held and enjoyed by said Assignee as fully and entirely as the same could have been held and enjoyed by the undersigned if this assignment had not been made, and particularly to execute and deliver to said Assignee all lawful documents including petitions, specifications, oaths, assignments, invention disclaimers, and lawful affidavits in form and substance which may be requested by said Assignee, to furnish said Assignee with all facts relating to said inventions or the history thereof and any and all documents, photographs, models, samples or other physical

exhibits which may be of said inventions, and to testify in any proceedings relating to said inventions, patent applications and Letters Patent.

The undersigned hereby grant the firm of FOLEY & LARDNER the power to insert in this Assignment any further identification which may be necessary or desirable to comply with the rules of the U.S. Patent and Trademark Office for recordation of this Assignment.

NAMES AND SIGNATURES OF INVENTORS		
Name: Tuula RYDE	Signature: <i>Tuula Ryde</i>	Date: 03 June, 2003
Name: Evan E. GUSTOW	Signature: <i>E. Gustow</i>	Date: 03 Jun 03
Name: Stephen B. RUDDY	Signature: <i>SR</i>	Date: 03 Jun 03
Name: Rajeev JAIN	Signature: <i>Rajeev Jain</i>	Date: 03 Jun 03
Name: Rakesh PATEL	Signature: <i>R. Patel</i>	Date: 03 JUNE 2003
Name: Michael John WILKINS	Signature:	Date:
NAMES AND SIGNATURES OF WITNESSES		
Name: Melissa Gillard	Signature: <i>Melissa Gillard</i>	Date: 03 June 2003
Name: CAROL WRAY	Signature: <i>C. Wray</i>	Date: 03 June 2003

Note: Prima facie evidence of execution may optionally be obtained by execution of this document before a U.S. Consul or before a local officer authorized to administer oaths whose authority is proved by a certificate from a U.S. Consul.

IPT-407:4/90(1)(modified)

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Att. Docket No.: 029318-0949

ASSIGNMENT - WORLDWIDE

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each undersigned inventor has sold and assigned, and by these presents hereby sells and assigns, unto

name and
address of
assignee(s)

ELAN PHARMA INTERNATIONAL, LTD.
WIL House, Shannon Business Park, Shannon, Co. Clare, Ireland
and
FOURNIER LABORATORIES IRELAND LTD.
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invention

NANOPARTICULATE FIBRATE FORMULATIONS

as set forth in this United States Patent Application

check one

☐ executed concurrently herewith

☐ executed on

☒ Serial No. 10/444,066 Filed 05/23/2003

said application for United States Letters Patent, including all divisional, renewal, substitute, continuation and Convention applications based in whole or in part upon said inventions or upon said applications, and any and all Letters Patent and reissues and extensions of Letters Patent granted for said inventions or upon said applications and every priority right that is or may be predicated upon or arise from said inventions, said applications, and said Letters Patent; said Assignee being hereby authorized to file patent applications in any or all countries on any or all said inventions in the name of the undersigned or in the name of said Assignee or otherwise as said Assignee may deem advisable, under the International Convention or otherwise; the Commissioner of Patents and Trademarks of the United States of America being hereby authorized to issue or transfer all said Letters Patent to said Assignee in accordance herewith; this assignment being under covenant, not only that full power to make the same is had by the undersigned, but also that such assigned right is not encumbered by any grant, license, or other right theretofore given, and that the undersigned will do all acts reasonably serving to ensure that the said inventions, patent applications and Letters Patent shall be held and enjoyed by said Assignee as fully and entirely as the same could have been held and enjoyed by the undersigned if this assignment had not been made, and particularly to execute and deliver to said Assignee all lawful documents including petitions, specifications, oaths, assignments, invention disclaimers, and lawful affidavits in form and substance which may be requested by said Assignee, to furnish said Assignee with all facts

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relating to said inventions or the history thereof and any and all documents, photographs, models, samples or other physical exhibits which may be of said inventions, and to testify in any proceedings relating to said inventions, patent applications and Letters Patent.

The undersigned hereby grant the firm of FOLEY & LARDNER the power to insert in this Assignment any further identification which may be necessary or desirable to comply with the rules of the U.S. Patent and Trademark Office for recordation of this Assignment.

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Name: Tuula RYDE	Signature:	Date:
Name: Evan E. GUSTOW	Signature:	Date:
Name: Stephen B. RUDDY	Signature:	Date:
Name: Rajeev JAIN	Signature:	Date:
Name: Rakesh PATEL	Signature:	Date:
Name: Michael John WILKINS	Signature: <i>Michael J. Wilkins</i>	Date: <i>29 Jul 2008</i>
NAMES AND SIGNATURES OF WITNESSES		
Name:	Signature:	Date:
Name:	Signature:	Date:

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